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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,048	05/01/2001	YongQi Mu	P-091-R	5200

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THERAVANCE, INC.
901 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,048	MU, YONGQI	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,14,16,17 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,14,16,17 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1/8/02* 3/4/02, 5/6/02
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-17 in the Reply and Amendment filed October 8, 2003 is acknowledged. Claims 1-12, 15 and 18-19 have been cancelled, claims 13, 16, 17, 20 and 21 have been amended, and new claims 22 and 23 have been added. Thus, claims 13, 14, 16, 17 and 20-23 are pending. The traversal is on the ground(s) that the inventions of Groups I and II have been classified in the same class and subclass, since the compounds of the invention are antibiotics, a search for the compounds would also produce prior art related to the use of the compounds as antibiotics, thus, a search and examination of the entire application can be made without serious burden; regarding additional election on the defined compound of formula (I) or (II), applicants indicate the amended claim now contains only formula (II), where R^a is alkylene and R^h is alkyl, and no specific reasons was given by the Examiner why this further restriction requirement is necessary (pages 6-8 of the reply). This is found persuasive, thus claims of Group I and II including compounds of formula (II), claims 13, 14, 16, 17 and 20-23 are examined, and the previous requirement for restriction mailed September 29, 2003 is vacated.

Informalities

The disclosure is objected to because of the following informalities:

2. Table 1 recites Compounds **1-4** at page 16, however, Schemes 1 and 2 at pages 42-43 also number the compounds as Compounds **1-4**, which are structurally different from Compounds **1-4** of Table 1. Compounds should be numbered consecutively throughout the whole specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13, 14, 16, 17 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for a glycopeptide of formula (II), where R^{20} is R^a-W-R^h and W is -S-C(=O)-, a pharmaceutical composition comprising the glycopeptide, and a method of treating a mammal having a bacterial disease by administering the glycopeptide or the pharmaceutical composition comprising the glycopeptide because the specification only discloses cursory conclusions without data supporting the findings, which state that the present invention provides novel disulfide or thioester glycopeptide derivatives, e.g., glycopeptides of formula (II), where R^{20} is R^a-W-R^h and W is -S-S- or -S-C(=O)-, having highly effective antibacterial activity and an improved mammalian safety profile, more specifically, the disulfide or thioester glycopeptide derivatives exhibit reduced tissue accumulation and nephrotoxicity when administered to a mammal, (page 2, line 24-page 3, line 2; pages 13-15). There are no indicia that the present application enables the claims in view of the thioester glycopeptide compounds and the method of treating a mammal having a bacterial disease by administering the thioester glycopeptide compounds as discussed in the stated rejection. The factors considered in determining whether undue experimentation is required, are summarized in

In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses unspecified variants regarding the thioester glycopeptide compounds and the effects of the glycopeptides in the treatment of various bacterial diseases, which are not adequately described or demonstrated in the specification.

(2). The absence or presence of working examples:

There are no working examples indicating the claimed variants and the methods in association with the variants, the specification has not demonstrated a thioester glycopeptide compound has been isolated and used for treating various bacterial diseases. The specification only indicates the mass spectrum data of four disulfide glycopeptide compounds (Table 1 and Example 1).

(3). The state of the prior art and relative skill of those in the art:

The prior art (e.g., references at page 2 of the specification) indicates a number of vancomycin or other glycopeptides have been made and used as antibiotics. However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide teachings on the identification of various thioester glycopeptide compounds made and the effects of the compounds in the treatment of various bacterial diseases to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass various thioester glycopeptide compounds and a method of treating a mammal having a bacterial disease by administering the glycopeptide compound, however, the identification of thioester glycopeptide compounds and the effects of compounds in the treatment of bacterial diseases are not adequately described in the specification, the invention is highly unpredictable regarding the effects of various thioester glycopeptide compounds.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a glycopeptide of formula (II), where R^{20} is R^a-W-R^h and W is -S-C(=O)-, a pharmaceutical composition comprising the glycopeptide, and a method of treating a mammal having a bacterial disease by administering the glycopeptide or the pharmaceutical composition comprising the glycopeptide. The specification indicates a glycopeptide such as vancomycin can be reductive alkylated using an aldehyde to give a glycopeptide that is alkylated at the saccharide-amine (pages 37-38), and aldehydes comprising a thioester group are either commercially available or can be prepared according to Scheme 2 (pages 42-43). The specification further disclose various pharmaceutical formulations comprising the glycopeptides (pages 44-54), preparation of disulfide glycopeptide compounds (Example 1), in vitro and in vivo determination of antibacterial activity of the test compound (Example 2); and determination of tissue accumulation of the test compound (Example 3). However, the specification has not demonstrated the identification of a thioester glycopeptide compound and the effect of the compound in the treatment of various bacterial diseases. Moreover, there are no working examples indicating the effects of these thioester glycopeptide compounds. Since the

specification fails to provide sufficient teachings on the identification of the thioester glycopeptide compound and the effect of the compound in treating bacterial diseases, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various thioester glycopeptide compounds in the claimed method.

(6). Nature of the Invention

The scope of the claims encompasses a thioester glycopeptide and a method of treating a mammal having a bacterial disease by administering the glycopeptide, but the specification does not demonstrate the effect of the thioester glycopeptide in the treatment. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, there is no working examples demonstrating the claimed variants and methods, the teaching in the specification is limited, and the effect of compound is not indicated, and therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various thioester glycopeptide compounds in the treatment of bacterial diseases.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 20 and 21 are indefinite because the claim lacks essential steps in the method of treating a mammal having a bacterial disease. The omitted step is outcome of the treatment.

Conclusions

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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October 26, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600